



PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Annie ANDRIEUX et al.

Group Art Unit: 4121

Application No.: 10/586,486

Examiner: J. CORNET

Filed: December 12, 2006

Docket No.: 128765

For: USE OF EPOTHILONES IN THE TREATMENT OF NEURONAL CONNECTIVITY DEFECTS SUCH AS SCHIZOPHRENIA AND AUTISM

**RESPONSE TO RESTRICTION AND ELECTION
OF SPECIES REQUIREMENT**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In reply to the January 6, 2009 Restriction and Election of Species Requirement,
Applicants provisionally elect Group IV, claim 21 with traverse.

A. Unity of Invention Standard

National stage applications filed under 35 U.S.C. §371 are subject to unity of invention practice as set forth in PCT Rule 13, and are not subject to U.S. restriction practice. See MPEP §1893.03(d). PCT Rule 13.1 provides that an "international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept." PCT Rule 13.2 states:

Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical

features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

A lack of unity of invention may be apparent "*a priori*," that is, before considering the claims in relation to any prior art, or may only become apparent "*a posteriori*," that is, after taking the prior art into consideration. *See MPEP §1850(II)*, quoting *International Search and Preliminary Examination Guidelines* ("ISPE") 10.03. Lack of *a priori* unity of invention only exists if there is no subject matter common to all claims. *Id.* If *a priori* unity of invention exists between the claims, or, in other words, if there is subject matter common to all the claims, a lack of unity of invention may only be established *a posteriori* by showing that the common subject matter does not define a contribution over the prior art. *Id.*

Furthermore, unity of invention only needs to be determined in the first place between independent claims, and not the dependent claims, as stated in ISPE 10.06:

Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of one or more other claims and contains a reference, preferably at the beginning, to the other claim or claims and then states the additional features claimed (Rule 6.4).

See also MPEP §1850(II). ISPE 10.07 further provides:

If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention.

See also MPEP §1850(II).

B. Restriction

The Restriction Requirement between Groups I, II, III, IV, and IV is not in accordance with U.S. practice for at least the following reasons.

First, As stated above, unity of invention only needs to be determined in the first place between independent claims, and not the dependent claims. Claims 16-24 depend from claim 15 and, therefore, the claims all share the subject matter of at least claim 15.

Second, the groupings themselves are erroneous because, among other things, claim 15, which is generic to all the claims, is only included in group I. Thus, Groups II, III, and IV are each related to the same general formula.

Third, the Office Action asserts that the epothilone compound of claim 17 does not define a contribution over the prior art in view of WO 00/66589. This assertion is improper because the compound recited in claim 17 is not necessarily common to each of the claims. The Office Action fails to address whether claim 15 defines a contribution over the prior art. Furthermore, the Office Action does not address the entirety of the subject matter common to all the claims. Specifically, claim 15 is directed to treating a neuronal connectivity defect by administering a therapeutic effective amount of an epothilone or derivative thereof. Although WO 00/66589 may disclose epothilone compounds, it does not appear to disclose treating neuronal connectivity defects, but instead discloses treating cancer and chronic inflammatory diseases. Moreover, the Office Action only asserts that formula (I) of claim 17 "shares similar structure" to that disclosed in WO 00/66589. However, the Office Action never addresses how "similar" the structures are or any reasoning as to why the differences between the structures would have been obvious. For at least these reasons, the Office Action fails to establish a *prima facie* lack of unity of invention.

Accordingly, all the claims share common subject matter and, therefore, *a priori* unity of invention exists between all the claims. Thus, for the present application, a lack of unity of invention may only be determined *a posteriori*, or in other words, after a search of the prior art has been conducted and it is established that all the elements of the independent claim are known. See ISPE 10.07 and 10.08.

The Office Action does not establish that each and every element of the subject matter that is common to independent claims X and Y is known in the prior art. Therefore, Applicants respectfully submit that lack of unity of invention has not been established, and thus a restriction requirement based on a lack of unity of invention is improper.

C. Election of Species

The species election requirement is also improper under PCT Rule 13. In general, restriction between species is not allowed under PCT Rule 13. Restriction between different embodiments (species) of an invention encompassed by a single independent claim is only proper under PCT Rule 13 if the independent claim expressly recites distinct embodiments (such as a Markush group) and the Office Action establishes that the distinct embodiments share no common subject matter that defines a contribution over the prior art. *See* ISPE 10.09; MPEP §1850(II). In this case, claim 15 is generic and does not recite distinct embodiments and, as discussed above, the Office Action fails to establish that claim 15 lacks a special technical feature. Therefore, the election of species requirement is also improper. Accordingly, the election of species requirement is improper and must be withdrawn.